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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

**[Docket No. DEA-386]**

**Schedules of Controlled Substances: Temporary Placement of 10 Synthetic**

**Cathinones into Schedule I**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final order.

**SUMMARY:** The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule 10 synthetic cathinones into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act (CSA). The 10 substances are: 4-methyl-*N*-ethylcathinone (“4-MEC”); 4-methyl-*alpha*-pyrrolidinopropiophenone (“4-MePPP”); *alpha*-pyrrolidinopentiophenone (“*α*-PVP”); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (“butylone”); 2-(methylamino)-1-phenylpentan-1-one (“pentedrone”); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (“pentylone”); 4-fluoro-*N*-methylcathinone (“4-FMC”); 3-fluoro-*N*-methylcathinone (“3-FMC”); 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (“naphyrone”); and *alpha*-pyrrolidinobutiophenone (“*α*-PBP”). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cathinones and their optical, positional, and geometric isomers, salts and salts of isomers into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As

a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities, and possess), or propose to handle these synthetic cathinones.

**DATES:** This final order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone (202) 598-6812.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority**

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of the DEA, who in turn has delegated her authority to the Deputy Administrator of the DEA. 28 CFR 0.100, Appendix to Subpart R of Part 0, Sec. 12.

## **Background**

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services

(HHS) of his intention to temporarily place a substance into schedule I of the CSA.<sup>1</sup> The Deputy Administrator transmitted notice of his intent to place 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP into schedule I on a temporary basis to the Assistant Secretary by letter dated November 7, 2013. The Assistant Secretary responded to this notice by letter dated December 4, 2013, and advised that based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP into schedule I of the CSA.

The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). As 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP under section 505 of the FDCA, 21 U.S.C. 355, the conditions of 21 U.S.C. 811(h)(1) have been satisfied. As required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule these 10 synthetic cathinones was published in the Federal Register on January 28, 2014. 79 FR 4429.

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<sup>1</sup> Because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this Final Order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Assistant Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP indicate that these 10 synthetic cathinones have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

### **Synthetic Cathinones**

Synthetic cathinones are  $\beta$ -keto-phenethylamine derivatives of the larger phenethylamine structural class (amphetamines, cathinones, 2C compounds, aminoindanes, etc.). Synthetic cathinones share a core phenethylamine structure with substitutions at the  $\beta$ -position,  $\alpha$ -position, phenyl ring, or nitrogen atom. The addition of a beta-keto ( $\beta$ -keto) substituent (i.e., carbonyl (C=O)) to the phenethylamine core structure along with substitutions on the alpha ( $\alpha$ ) carbon (C) atom or the nitrogen (N)

atom produce a variety of substances called cathinones or synthetic cathinones. Many synthetic cathinones produce pharmacological effects substantially similar to the schedule I substances cathinone, methcathinone, and 3,4-methylenedioxymethamphetamine (MDMA) and schedule II stimulants amphetamine, methamphetamine, and cocaine. 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentytone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP are synthetic cathinones and are structurally and pharmacologically similar to amphetamine, MDMA, cathinone, and other related substances. Accordingly, these synthetic cathinone substances share substantial similarities with schedule I and schedule II substances with respect to desired and adverse effects. In general, desired effects reported by abusers of synthetic cathinone substances include euphoria, sense of well-being, increased sociability, energy, empathy, increased alertness, and improved concentration and focus. Abusers also report experiencing unwanted effects such as tremor, vomiting, agitation, sweating, fever, and chest pain. Other adverse or toxic effects that have been reported with the abuse of synthetic cathinones include tachycardia, hypertension, hyperthermia, mydriasis, rhabdomyolysis, hyponatremia, seizures, altered mental status (paranoia, hallucinations, delusions), and even death. These synthetic cathinone substances have no known medical use in the United States but evidence demonstrates that these substances are being abused by individuals. There have been documented reports of emergency room admissions and deaths associated with the abuse of synthetic cathinone substances.

Products that contain synthetic cathinones have been falsely marketed as “research chemicals,” “jewelry cleaner,” “stain remover,” “plant food or fertilizer,” “insect repellants,” or “bath salts.” These products are sold at smoke shops, head shops,

convenience stores, adult book stores, and gas stations and can also be purchased on the Internet. These substances are commonly encountered in the form of powders, crystals, resins, tablets, and capsules.

From January 2010 through December 2013, according to the System to Retrieve Information from Drug Evidence<sup>2</sup> (STRIDE) data, there are 377 exhibits for 4-MEC; 125 exhibits for 4-MePPP; 689 exhibits for  $\alpha$ -PVP; 75 exhibits for butylone; 304 exhibits for pentedrone; 121 exhibits for pentylone; 37 exhibits for FMC<sup>3</sup>; 24 exhibits for naphyrone; and 37 exhibits for  $\alpha$ -PBP. From January 2010 through December 2013, the National Forensic Laboratory Information System<sup>4</sup> (NFLIS) registered 9,113 reports containing these synthetic cathinones (4-MEC—1,952 reports; 4-MePPP—289 reports;  $\alpha$ -PVP — 4,536 reports; butylone—495 reports; pentedrone—1,167 reports; pentylone—238 reports; FMC<sup>5</sup>—292 reports; naphyrone—44 reports;  $\alpha$ -PBP —100 reports) across 42 States.

#### **Factor 4. History and Current Pattern of Abuse**

4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP are synthetic cathinones that emerged on the United States' illicit drug market around the time of the temporary scheduling of mephedrone, MDPV, and methylone on October 21, 2011. 76 FR 65371. Mephedrone and MDPV were permanently placed in schedule I on July 9, 2012, by the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), and methylone was permanently placed in

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<sup>2</sup> STRIDE is a database of drug exhibits sent to the DEA laboratories for analysis. Exhibits from the database are from the DEA, other Federal agencies, and some local law enforcement agencies. STRIDE data was queried on 2/5/2014 by date submitted to Federal forensic laboratories.

<sup>3</sup> FMC refers to both 3-FMC and 4-FMC.

<sup>4</sup> NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories across the country. NFLIS State and local forensic drug reports were queried on 2/6/2014.

<sup>5</sup> FMC refers to both 3-FMC and 4-FMC.

schedule I by the DEA on April 12, 2013 (78 FR 21818). These synthetic cathinone substances, like the schedule I synthetic cathinones (mephedrone, methylone, and MDPV), are promoted as being a “legal” alternative to cocaine, methamphetamine, and MDMA. Products that contain 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP are falsely marketed as “research chemicals,” “jewelry cleaner,” “stain remover,” “plant food or fertilizer,” “insect repellants,” or “bath salts.” They are sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations, and can also be purchased on the Internet under a variety of product names (e.g., “White Dove,” “Explosion,” and “Tranquility”). They are commonly encountered in the form of powders, crystals, resins, tablets, and capsules. The packages of these commercial products usually contain the warning “not for human consumption.”

Information from published scientific studies indicates that the most common routes of administration for synthetic cathinone substances is ingestion by swallowing capsules or tablets or nasal insufflation by snorting the powder. Other methods of intake include intravenous or intramuscular injection, rectal administration, and swallowing via ingestion by “bombing” (wrapping a dose of powder in paper).

There is evidence that these synthetic cathinone substances are abused alone or ingested with other substances including other synthetic cathinones, pharmaceutical agents, or other recreational substances. Substances found in combination with 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, or naphyrone are: other synthetic cathinones (e.g., methylone and MDPV), common cutting agents (e.g.,



lidocaine, caffeine, lignocaine, ephedrine, etc.), or other recreational substances (e.g., cocaine, methamphetamine, and amphetamine).

Evidence from poison centers and published reports suggest that the primary users of synthetic cathinones are youths and young adults. Synthetic cathinone exposures reported to the Texas Poison Center Network during 2010 and 2011 involved mostly adolescents (12 to 19-years-old) and young adults (mean age was 30-years-old). A survey of college students reported that the lifetime use (used at least once) of synthetic cathinones among college students (at a large Southeastern United States university) is 25 out of 2,349 students surveyed. A national survey on drug use by the Monitoring the Future (MTF)<sup>6</sup> research program showed that 0.2% of full-time college students (one to four years past high school) used synthetic cathinone substances in 2012. Similarly, the use of synthetic cathinone substances among 8<sup>th</sup>, 10<sup>th</sup>, and 12<sup>th</sup> grade students, and young adults (non-college peers aged 19 to 28-years-old) was 0.8%, 0.6%, 1.3%, and 0.8%, respectively.

#### **Factor 5. Scope, Duration and Significance of Abuse**

4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP, like the schedule I cathinones mephedrone, methylone, and MDPV, are popular recreational drugs. Evidence that these synthetic cathinone substances are being abused is indicated by law enforcement encounters of these substances. Forensic laboratories have analyzed drug exhibits received from State, local, and Federal law enforcement agencies and confirmed the presence of 4-MEC, 4-MePPP,

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<sup>6</sup> MTF is a research program conducted by the University of Michigan's Institute for Social Research under grants from NIDA. MTF tracks drug use trends among American adolescents in the 8th, 10th, and 12th grades and high school graduates into adulthood by conducting nationwide surveys.

$\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP in these exhibits.

STRIDE registered 1,789 drug exhibits pertaining to the trafficking, distribution and abuse of 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP from January 2010 to December 2013.<sup>7</sup> Specifically, in 2010, STRIDE contains four reports related to 4-MEC and none for the other nine substances. However, in 2011, there were 216 reports related to these 10 substances, and in 2012, there were 1,314 reports. In 2013, there were 255 reports.

NFLIS registered over 9,000 reports from State and local forensic laboratories identifying these substances in drug-related exhibits for the period from January 2010 to December 2013, across 42 States. Specifically, in 2010, NFLIS registered 13 reports from 5 States containing many of these synthetic cathinone substances.<sup>8</sup> In 2011, there were 800 reports from 32 States related to these substances registered in NFLIS, in 2012 there were 5,519 reports from 41 States, and in 2013 there were 2,781 reports from 42 States.

Additionally, large seizures of these substances have occurred by the United States Customs and Border Protection (CBP). At selected United States ports of entry, CBP encountered several shipments of products from April 2010 to November 2013 containing these synthetic cathinone substances (4-MEC—78 encounters; 4-MePPP—8 encounters;  $\alpha$ -PVP —40 encounters; butylone—21 encounters; pentedrone—18 encounters; pentylone—10 encounters; FMC<sup>9</sup>—13 encounters; naphyrone—3 encounters;  $\alpha$ -PBP —11 encounters), thus indicating the appeal of these substances.

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<sup>7</sup> STRIDE data was queried on 2/5/2014 by date submitted to Federal forensic laboratories.

<sup>8</sup> NFLIS State and local forensic drug reports were queried on 2/6/2014.

<sup>9</sup> FMC refers to both 3-FMC and 4-FMC.

Most of the shipments of these synthetic cathinones originated overseas and were destined for delivery throughout the United States to States including Arizona, Arkansas, California, Colorado, Florida, Hawaii, Idaho, Illinois, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, Oklahoma, Oregon, Texas, Virginia, Washington, and Wyoming.

Concerns over the abuse of these synthetic cathinone substances have prompted many States to regulate them. As of June 24, 2013, more than half of the States in the United States have emergency scheduled or enacted legislation placing regulatory controls on some or many of the 10 synthetic cathinones that are the subject of this final order. In addition, due to the use of synthetic cathinones by service members, the United States Armed Forces has prohibited the use of synthetic cathinones for intoxication purposes.

**Factor 6. What, if Any, Risk There is to the Public Health**

Available evidence on the overall public health risks associated with the use of synthetic cathinones indicates that 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP can cause acute health problems leading to emergency department admissions, violent behaviors causing harm to self or others, or death. For example, individuals have presented at emergency departments following exposure to some of these synthetic cathinone substances or products containing them. In addition, products containing these synthetic cathinone substances often do not bear labeling information regarding their ingredients and, if they do, they may not list the active synthetic ingredients or identify the health risks and potential hazards associated with these products. Acute effects of these substances are those

typical of sympathomimetic agents (e.g., cocaine, methamphetamine, and amphetamine) and include, among other effects, tachycardia, headache, bruxism (teeth grinding), palpitations, agitation, anxiety, insomnia, mydriasis, tremor, fever or sweating, and hypertension. Other effects, with public health risk implications, that have been reported from the use of synthetic cathinone substances include vomiting, palpitations, chest pain, hyperthermia, rhabdomyolysis, hyponatremia, seizures, and altered mental status (paranoia, hallucinations, and delusions). Finally, the possibility of death for individuals abusing 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP indicates that these substances are serious public health threats. Some of these synthetic cathinone substances have been directly or indirectly implicated in the death of individuals. For example, a 24-year-old female died after ingesting two capsules of what she believed to be “Ecstasy” but was subsequently confirmed to be a mixture of methylone and butylone. The cause of death determined by the medical examiner was serotonin syndrome secondary to methylone and butylone ingestion. A 21-year-old male who ingested butylone for suicidal intentions died after he developed seizures and suffered a cardiac and respiratory arrest. The cause of death was reported as multi-organ failure resulting from malignant serotonin syndrome.

### **Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety**

Based on the above summarized data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted

medical uses for these synthetic cathinones in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b). Based on available data and information for 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP, the Deputy Administrator has made the determination that these 10 synthetic cathinones have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Deputy Administrator through a letter dated November 7, 2013, notified the Assistant Secretary of the DEA's intention to temporarily place these 10 synthetic cathinones in schedule I.

## **Conclusion**

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily place 10 synthetic cathinones, 4-MEC, 4-MePPP,  $\alpha$ -PVP, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP into schedule I of the CSA, and finds that placement of these synthetic cathinones into schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic cathinones into schedule I to avoid an imminent hazard to the public

safety, the final order temporarily scheduling these substances will be effective on the date of publication in the Federal Register, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done “on the record after opportunity for a hearing” conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

### **Requirements for Handling**

Upon the effective date of this final order, 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, exporting, research, conduct of instructional activities, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, conducts instructional activities with, or possesses), or desires to handle, 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP, must be registered with the DEA to conduct such activities

pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP, and is not registered with the DEA, must submit an application for registration and may not continue to handle 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA.

2. *Security.* 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71-1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants shall have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], to comply with all labeling and packaging requirements.

4. *Inventory.* Every DEA registrant who possesses any quantity of 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP on the effective date of this order, must take an inventory of all stocks of these substances on hand as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d). Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements.

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, and  $\alpha$ -PBP) on hand on a biennial basis, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

5. *Records.* All DEA registrants must maintain records with respect to 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304, 1307, and 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Current DEA registrants authorized to handle 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

6. *Reports.* All DEA registrants who manufacture or distribute 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].



7. *Order Forms.* All registrants who distribute 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

8. *Importation and Exportation.* All importation and exportation of 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Quota.* Only registered manufacturers may manufacture 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

10. *Criminal Liability.* Any activity involving 4-MEC, 4-MePPP,  $\alpha$ -PVP, butylone, pentedrone, pentylone, 4-FMC, 3-FMC, naphyrone, or  $\alpha$ -PBP not authorized by, or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

### **Regulatory Matters**

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the Federal

Register of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety. Further, the DEA believes that this temporary scheduling action final order is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Pursuant to section 808(2) of the Congressional Review Act (CRA), “any rule for which an agency for good cause finds...that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety from new or designer drugs or abuse of those drugs. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA’s need to move quickly to place these substances into schedule I because they pose a threat to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order shall take effect immediately upon its publication.

#### **List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

#### **PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Amend § 1308.11 by adding new paragraphs (h)(19) through (h)(28), to read as follows:

§ 1308.11 Schedule I.

\* \* \* \* \*

(h) \* \* \*

(19) 4-methyl-*N*-ethylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers – 1249 (Other names: 4-MEC; 2-(ethylamino)-1-(4-methylphenyl)propan-1-one)

(20) 4-methyl-*alpha*-pyrrolidinopropiophenone, its optical, positional, and geometric isomers, salts and salts of isomers – 7498 (Other names: 4-MePPP; MePPP; 4-methyl- $\alpha$ -pyrrolidinopropiophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one)

(21) *alpha*-pyrrolidinopentiophenone, its optical, positional, and geometric isomers, salts and salts of isomers – 7545 (Other names:  $\alpha$ -PVP;  $\alpha$ -pyrrolidinovalerophenone; 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)

(22) Butylone, its optical, positional, and geometric isomers, salts and salts of isomers – 7541 (Other names: bk-MBDB; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one)

(23) Pentedrone, its optical, positional, and geometric isomers, salts and salts of isomers – 1246 (Other names:  $\alpha$ -methylaminovalerophenone; 2-(methylamino)-1-phenylpentan-1-one)

(24) Pentylone, its optical, positional, and geometric isomers, salts and salts of isomers – 7542 (Other names: bk-MBDP; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one)

(25) 4-fluoro-*N*-methylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers – 1238 (Other names: 4-FMC; flephedrone; 1-(4-fluorophenyl)-2-(methylamino)propan-1-one)

(26) 3-fluoro-*N*-methylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers – 1233 (Other names: 3-FMC; 1-(3-fluorophenyl)-2-(methylamino)propan-1-one)

(27) Naphyrone, its optical, positional, and geometric isomers, salts and salts of isomers – 1258 (Other names: naphthylpyrovalerone; 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one)

(28) *alpha*-pyrrolidinobutiophenone, its optical, positional, and geometric isomers, salts and salts of isomers – 7546 (Other names:  $\alpha$ -PBP; 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one)

Dated: February 28, 2014

Thomas M. Harrigan,  
Deputy Administrator.

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